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Risk categorization predicts disability in pain-associated functional gastrointestinal disorders (FGIDs) after 6 months

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Abstract

Introduction—For a large portion of youth, pain-associated functional gastrointestinal disorders (FGIDs) are associated with significant impairment over time. Clinically feasible methods to categorize youth with FGIDs at greatest risk for persistent pain-related impairment have not yet been identified.

Methods—Measures of functional disability, pain intensity and anxiety were collected on 99 patients with FGIDs (ages 8–18) during a visit to a pediatric gastroenterology office to assess for the presence of risk. Follow-up data was obtained on a subset of this sample (n=64) after 6 months, either in person or via mail. This study examined whether a greater number of risk factors at baseline predicted greater pain-related disability at follow-up.

Results—Patients were divided into 4 groups based on number of risk factors present at the initial assessment: zero (18.2%), one (24.2%), two (26.3%), and three (31.3%). The presence of 2 or 3 risk factors significantly predicted greater disability at follow-up compared to those with 0

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NRC- study concept/design, acquisition of data, analysis/interpretation of data, drafting manuscript, critical revision of manuscript, statistical analysis, obtained funding, study supervision.

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risk factors ($R^2 = 0.311$) and those with just 1 risk factor (*Cohen's d* values of -1.07 and -1.44 , respectively).

Discussion—A simple approach to risk categorization can identify youth with FGIDs who are most likely to report increased levels of pain-related impairment over time. These findings have important clinical implications that support the utility of a brief screening process during medical care to inform referral for targeted treatment approaches to FGIDs.

Keywords

pediatric; functional abdominal pain; pain-associated functional gastrointestinal disorders (FGIDs); disability; anxiety

Pain-associated functional gastrointestinal disorders (FGIDs) are a common set of pediatric pain conditions affecting ~13.5% of youth¹ and are associated with significant functional impairment^{2–6}. FGIDs are characterized by a high prevalence of anxiety^{7–10} that adversely impacts disability in this population^{11–14} even over the long term^{12, 14–16}. For a 25–45% of affected youth, pain and impairment persist for five years or longer^{17, 18}. Unfortunately, children who are at greatest risk for persistent disability are not properly identified in current patterns of care^{19, 20}.

Categorizing patients' level of risk based on factors known to impact functional outcomes may be a useful method for capturing youth with FGIDs who are at increased risk for poor outcomes. The chronic pain grading system (CPG) is a validated risk categorization system that was originally developed for adults who experience chronic pain^{21–23}. More recently, the CPG^{24, 25} and other brief risk classification approaches²⁶ have been studied in pediatric samples but not specifically in FGIDs, nor do these screening approaches assess for anxiety, which is known to be an important contributor to disability in FGIDs. The CPG algorithm²¹ traditionally calculates degree of risk based on pain intensity and pain-related disability. Thus, it is important to develop a screening approach that assesses for known risk factors specific to pain (intensity and disability) *in addition to* anxiety, which is known to impact functioning in youth with FGIDs.

Although a lengthy assessment of anxiety may be impractical in a medical setting, use of a brief screening instrument may be feasible. Our prior research has shown a screening measure, the Screen for Child Anxiety and Related Emotional Disorders (SCARED)^{27, 28}, can accurately capture anxiety in youth with FGIDs which corresponds to increased pain and disability in a cross-sectional study⁸. The primary objective of the current study was to examine risk status in patients with FGIDs at an initial visit to a gastroenterologist and assess functional disability 6 months later. To assess risk, the current study tested a CPG specific to youth with FGIDs. Categorization of risk is based on youth report of pain intensity, disability, *and* anxiety. We hypothesized that those youth with higher numbers of risk factors would have the highest levels of pain-related disability after 6 months when compared to those with fewer risk factors. We also explored the association between number of baseline risk factors and other indicators of impairment at follow-up (healthcare utilization and school absences).

METHODS

Procedures

Baseline data was collected in person during a pediatric gastroenterology office visit at a large Midwestern children's hospital as a part of a larger Institutional Review Board (IRB) approved protocol investigating psychosocial factors impacting impairment in youth with FGIDs. Six month follow up data was completed by families during a follow up visit to the gastroenterology clinic or by mail if they did not have a scheduled clinic appointment in that time frame. A 6 month follow-up was employed as this timeframe is typically long enough to diagnose any undiscovered organic disease. Written parent permission and child assent were obtained.

Participants

We collected baseline data on 100 patients with FGIDS (ages 8–18), originally described in a previously published study⁸. Of these, 99 patients completed measures of functional disability, pain intensity and anxiety, and were included in the current study. Patients were diagnosed with FGIDs by one of three participating pediatric gastroenterologists informed by Rome III guidelines²⁹. Patients were ineligible for the study if 1) they had a significant medical condition(s) with an identifiable organic cause (e.g., inflammatory bowel diseases such as ulcerative colitis and Crohn's disease, celiac disease, eosinophilic esophagitis, H.pylori, etc...), or 2) if patients had significant developmental delay or cognitive impairment. We obtained follow-up data on 64 of these participants either during an in-clinic visit (n=11) or via mail/phone (n=53).

Measures

Demographic Information—Detailed demographic and background information (including medication usage) were collected from the parent and from the patient's electronic medical chart.

Functional Disability Inventory- Child Version (FDI-C)—The FDI-C is a 15-item validated measure which assesses patient-reported physical functioning and difficulty completing activities in the past few days due to pain³⁰. Responses to each item range from 0 (no trouble) to 4 (impossible), and are summed to create a total disability score. Scores range from 0–60, with 0–12 indicating no/minimal disability, 13–29 indicating moderate disability, and 30 or higher indicating severe disability³¹. Risk was defined as presence of at least moderate disability (FDI >12).

Numeric Rating Scale (NRS) Pain Intensity – Child Report—The NRS pain rating scale assesses average and highest pain intensity (0–10 scale) over the last two weeks, with “0” indicating no pain, and “10” reflecting worst possible pain. The NRS pain intensity scale is recommended for use in clinical studies of pain in school-age children³². Risk was identified as a characteristic pain rating (mean of the average and highest pain) of 5.

Screen for Child Anxiety Related Disorders –Child Report (SCARED- C)—The SCARED is a widely used screening instrument for clinically significant anxiety symptoms

in youth based on the DSM-IV-TR³³, and has been validated for use in children ages 8 and above²⁷. The SCARED has been validated in a pediatric pain sample³⁴ and has been used in clinical samples of youth with FGIDs^{8, 9, 35}. Patients report frequency of anxiety symptoms over the past three months on a 41-item measure with responses including “not true” “sometimes true”, and “often true”. Total scores range from 0–82, with higher scores reflecting greater levels of anxiety. For the current study, risk was defined as presence of clinically significant anxiety (e.g., total score ≥ 25), based on optimal sensitivity and specificity at this cut-off^{27, 28}.

Healthcare Utilization

At follow-up, the primary caregiver completed information on patient healthcare utilization in the past three months, based on a semi-structured interview developed specifically with pediatric pain populations in mind³⁶. In the current study, the total number of medical visits in the past three months was calculated by summing the number of healthcare provider visits, emergency room visits, and hospitalizations. The number of caregiver reported school absences due to pain in the past three months was also examined.

Categorization of Risk

Youth were categorized by number of risk factors, ranging from 0 to 3. Drawing from prior research, we categorized presence of risk in each of 3 factors based on 1) characteristic pain intensity (the mean of worst and average pain intensity ≥ 5 out of 10), 2) at least moderate pain-related disability using established clinical cut-offs for the FDI (FDI ≥ 12), and 3) presence of clinically significant anxiety using the SCARED (≥ 25). Thus, in our investigation, patient risk ranged from no risk (characteristic pain <5 , minimal to no pain-related disability, and absence of clinically significant anxiety) to all 3 risk factors present (characteristic pain ≥ 5 , at least moderate disability, and presence of clinically significant anxiety). Of note, patients with one or two risk factors were combined regardless of the type of risk factors present because it is hypothesized that the *accumulation* of risk factors rather than the type of risk factors predict increased impairment.

Data Analysis

Data analyses were conducted using Mplus 6.12³⁷. Differences in disability levels at follow-up were examined between each risk factor group (1, 2, 3) compared to the group with 0 risk factors via an SEM equivalent of an ANCOVA, with patient age as the covariate. Age was controlled for in these analyses given our prior research in this sample demonstrating that age is significantly correlated with functional disability in youth with FGIDs⁸. Missing data was handled through maximum likelihood parameter estimation with a ‘saturated correlates’ model to increase the likelihood of the missing at random (MAR) assumption being met³⁸. Post-hoc analyses involved examining all other possible pairwise comparisons among risk factor groups on functional disability at follow-up. False Discovery Rate (FDR) was used to control for Type 1 errors. Significant findings were categorized by confidence intervals that do not include zero. Effect sizes (*Cohen’s d*) were computed for significant post hoc comparisons. Lastly, risk categories were explored in relation to healthcare utilization and school absences.

RESULTS

Demographic Characteristics

Table 1 presents sociodemographic characteristics for the total sample and for the subset of patients that for whom follow up data was obtained. There were no significant differences between the groups for age, gender, ethnicity and FGIDs diagnosis. The majority of the sample was female and Caucasian. At six month follow-up, the mean age of participants was 13.63. The majority (>75%) of the sample reported pain symptoms for one year in duration or longer. Although a large portion of youth (>40%) with FGIDs were not diagnosed with a specific FGID subtype, the most common FGIDs subtype diagnoses were Irritable Bowel Syndrome (IBS), followed by Functional Dyspepsia and Abdominal Migraine.

On average, youth and their caregivers reported taking a total of 3.21 (SD=2.32) medications for their FGID condition. The most commonly reported medications included acid-reduction therapy (50.1%), non-stimulating laxatives (47.5%) antispasmodic agents (38.4%), and low doses of psychotropic agents (23.2%). Families also reported use of anti-nausea medications (13.1%) fiber (8.1%), probiotics (8.1%), peppermint oil (3.0%), and antidiarrheal medications (2.0%).

Clinical Characteristics

When the sample was examined in aggregate, reductions in disability, pain, and anxiety scores were noted from baseline to follow-up. At the initial visit (baseline), the mean functional disability score for the total sample was 13.94 (SD 9.71), suggestive of moderate levels of pain-related disability (13–29). At follow-up, the average functional disability was 9.77 (SD 10.11), suggestive of minimal levels of pain-related disability³¹. Similarly, the baseline characteristic pain intensity was 5.27/10 (SD=2.20), and the mean anxiety score was 28.04 (SD=15.50), indicative of clinically significant levels of anxiety. At follow up, characteristic pain intensity was 3.63/10 (SD=2.33) and the average anxiety score was 24.79 (SD=15.61).

Risk Status

Patients were divided into 4 groups based on the number of risk factors at baseline: zero (18.2%) one (24.2%), two (26.3%), and three (31.3%; See Table 2). Characteristic pain intensity, disability, and anxiety levels at baseline and follow-up are presented for the sample based on number of risk factors at the initial visit (Table 2). These data suggests that patients with a higher number of risk factors at the initial visit report higher levels of pain, anxiety, and disability at baseline and follow-up. It is noteworthy that presence of at least 2 risk factors generally corresponds to increased pain levels and moderate functional disability whereas presence of all three risk factors generally indicates clinical elevations in anxiety *in addition* to presence of the other risk factors (pain and disability). These data suggest that clinical elevations in anxiety appear to categorize individuals with the highest number of risk factors. However, it is important to note that while presence of clinically significant anxiety corresponds to increased pain levels and disability at a single visit⁸, clinical anxiety alone was not a significant predictor of greater disability at follow-up in the current investigation.

Baseline Risk Predicting Disability at 6 Months

In general, a greater number of risk factors at baseline predicted increased functional disability at follow-up (See Table 3). When controlling for patient age, the omnibus test (R^2 value = 0.311) revealed that presence of 2 ($p < 0.05$) or 3 ($p < 0.01$) risk factors significantly predicted greater disability at follow-up when compared with 0 risk factors. However, there was no significant difference in disability levels after 6 months in individuals with 0 risk factors compared to those with 1 risk factor.

Follow-up analyses using pairwise comparisons demonstrated that presence of either 2 or 3 risk factors at baseline significantly predicted greater disability at follow-up compared with just 1 risk factor (both p 's < 0.01 ; *Cohen's d* values of -1.07 and -1.44 , respectively). However, presence of all 3 risk factors did not significantly predict greater disability levels after six months when compared with the presence of 2 risk factors.

Exploratory Analysis

School absences and healthcare utilization were also examined across risk groups. Although there were no statistically significant differences between groups, youth with 0 or 1 risk factors had less than one school absence due to pain (.75 and 0.45 days, respectively) on average in the past three months whereas those with two or three risk factors reported more than four days of school absences in the same time period (4.77 and 5.9 days, respectively). A similar trend was observed for the number of medical visits reported in the past three months, with those with two or three risk factors having a higher number of medical visits (3.71 and 2.95 visits, respectively) compared with those who had zero (1.58 visits) or one risk (1.71 visits) factors.

DISCUSSION

This study utilized an adapted CPG algorithm to classify risk in pediatric patients with FGIDs during an evaluation at a gastroenterology clinic. We found that patients with FGIDs and *all three key risk factors* reported significantly higher levels of pain-related disability six months later. It is important to note that while anxiety alone does not predict sustained disability, anxiety in combination with other known risk factors (pain intensity, disability) in pediatric chronic pain predicts persistent functional impairment. Thus, this study suggests a pain grading system specifically tailored to the risk factors inherent in pediatric FGIDs (i.e., pain intensity, disability, *and* anxiety) can identify youth that have the greatest probability of ongoing or increased pain-related impairment over time. Thus, a child with an FGID who presents to subspecialty care with pain, disability, and comorbid anxiety, may be at the greatest risk for long-term impairment. This study also highlights the feasibility of using a brief screening process (~10 minutes), which can be readily incorporated into a medical clinic visit to provide timely and valuable information for clinicians to appropriately identify and triage at-risk patients. For example, those patients who present to medical care with all three risk factors present may benefit from receiving a more comprehensive care approach, including use of behavioral medicine interventions to target pain coping and anxiety.

These findings are also noteworthy given that when patient outcomes are explored in aggregate, the sample as a whole tends to improve over the course of time, suggesting that the needs of a subset of patients might be overlooked or minimized in the absence of a risk classification system. However, it becomes readily apparent that patients with the greatest number of risk factors demonstrate higher levels of pain-related disability over time. These findings are in line with prior investigations utilizing more comprehensive assessment processes to identify patients with FGIDs at greater risk for poor outcomes ^{2, 39}. The current study advances the field by assessing risk using a *brief* clinical screening process of risk factors tailored to pediatric FGIDs that can be readily employed in medical settings. Further, these findings suggest that pain-specific factors (e.g., disability, intensity) alone do not fully account for the impact of pain on the child's decision to engage in daily activities (e.g., participation in social events, school attendance, and physical activities). Instead, pain-related factors in combination with anxiety predict the youth with FGIDs and the most debilitating pain experience over the long term.

Further, these findings suggest that that level of risk in pediatric FGIDs is approximately evenly split across the four groups, with approximately 20%–30% of patients falling into each risk category. Thus, even in a sample of youth with FGIDs who are all presenting to subspecialty care, and therefore may be considered relatively homogeneous, a substantial portion (i.e., those with lower levels of risk) may improve with usual medical care. Similarly, providing additional intervention and care to patients with increased levels beyond traditional clinical care may be optimal for improving outcomes in the >50% of patients who present with either two or three risk factors at an initial gastroenterological evaluation. Of the nearly one third of patients with all three risk factors present, a comprehensive approach to assessment and treatment of both pain-related symptoms and anxiety symptoms may be critical to improve outcomes for afflicted youth.

Results of the current study should be interpreted in the context of a few limitations. The modest sample size and data collection from a single pediatric gastroenterology division may limit generalizability, though it should be noted that data collection occurred across several providers, clinics, and clinic locations to facilitate generalizability of the results. Similarly, follow-up data were only collected on two thirds of the original participants. However, sociodemographic characteristics are similar for our total sample and for the subset we collected at follow-up. Consistent with prior investigations of pediatric FGIDs ^{2, 9}, the sociodemographic composition of the sample was largely homogeneous (i.e., female, Caucasian), and it is unclear if study findings would be similar in male participants or those of various racial and ethnic backgrounds. Of all the measures used, the anxiety screening measure is relatively lengthy (41 items) but is psychometrically sound. Although a briefer version of the SCARED ²⁸ and other brief measures of anxiety exist ⁴⁰, there is less support for the use of clinically meaningful cutoffs to assign risk. In our experience, this measure is easily administered to patients (e.g., in the waiting room prior to their appointment) and provides readily interpretable results to the health care team at the point of service, allowing for actionable treatment planning. We also note that other factors, both pain-specific (i.e., pain frequency) and psychosocial, may play a role in predicting impairment but we believe this brief system accurately captures the risk factors most predictive of sustained impairment in our population.

Future directions include employing a screening approach that is embedded in subspecialty care and can be extended to other medical care settings (e.g., primary care). It will be critical to examine whether the algorithm for assessing risk of sustained impairment patients with FGIDs who present to subspecialty care is also applicable for capturing risk in patients who present to pediatric primary care settings or if modifications and adjustments need to be made to the algorithm as it is utilized in different settings. Perhaps presence of fewer risk factors in a primary care setting may signal additional intervention to prevent the transition from acute pain to a chronic pain condition requiring more extensive management at the subspecialty level.

These findings may also have useful applications for devising tailored and targeted care approaches (e.g., stepped and stratified care) for children with FGIDs. For example, youth with presence of 0 or 1 risk factors may benefit from a lower-level intervention (i.e., patient education incorporated into their medical visit), whereas patients with 2 or 3 risk factors may benefit from a more intensive approach that may include behavioral management of anxiety and pain symptoms, such as cognitive behavioral therapy for pain^{41–43}. Thus, the appropriate identification and triaging of patients who may benefit most from this intervention may be a clinically meaningful and cost-effective method to delivering such care.

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What is known about this subject?

- Pain-associated functional gastrointestinal disorders (FGIDs) are impairing pain conditions for a significant number of youth.
- Pain and functional disability are known risk factors that correspond to increased impairment over time in pediatric chronic pain populations.
- In youth with FGIDs, pain-related impairment is magnified in the presence of anxiety.

What are the new findings and/or what is the impact on clinical practice?

- A risk algorithm examining pain, disability and anxiety predicts higher levels of pain-related impairment in youth with FGIDs.
- A brief screening process that can be readily integrated into medical care can identify the risk status of pediatric FGID patients.
- These findings may inform tailored approaches to care depending on patient's risk level.

Table 1

Sample characteristics in youth with FGIDs at baseline and follow-up. Patients were predominantly Caucasian and female. There were no differences in sociodemographic characteristics between participants who participated in the initial evaluation and follow-up.

	Baseline (N=99)	Follow-up (N=64)
Gender		
Female	73(73.74)	48 (75.00)
Age M(SD)	13.03(3.14)	13.63(3.15)
Ethnicity		
Caucasian	87(87.89)	55 (85.94)
Biracial	1(1.01)	4 (6.25)
Asian American	3(3.03)	3 (4.69)
Hispanic/Latino	3(3.03)	1 (1.56)
African American	4(4.04)	1 (1.56)
Pain Duration		
3–6 months	17(17.17)	5 (8.33)
7–11 months	9(9.09)	6 (10.00)
1–3 years	33(33.33)	24 (40.00)
>3 years	40(40.04)	25 (41.67)
Pain Diagnosis		
FAP (no subtype)	50(50.05)	26 (40.63)
IBS	39(39.39)	27 (42.19)
Functional Dyspepsia	6(6.06)	7 (10.94)
Abdominal Migraine	4(4.04)	4 (6.25)
Pain Frequency		
Once a month	5(5.05)	8 (19.04)
Several times a month	6(6.06)	7 (16.67)
Once a week	10(10.10)	5 (11.90)
Several times a week	22(22.22)	14 (33.33)
Daily	56(56.57)	8 (19.05)

Note. Values N(%) unless otherwise indicated; FGIDs=pain-related functional gastrointestinal disorders; IBS = irritable bowel syndrome. For pain duration/frequency, percentages were calculated accounting for missing data, n=22 in the case of pain frequency and n=4 in the case of pain duration.

Table 2

Outcomes of youth with FGIDs based on number of risk factors at baseline. In general, participants with the greatest number of risk factors at baseline had higher levels of disability, pain and anxiety.

6 Month Outcomes	Number of Baseline Risks			
	<u>0</u>	<u>1</u>	<u>2</u>	<u>3</u>
Baseline	N=18(18.2%)	N=24(24.2%)	N=26(26.3%)	N=31(31.3%)
FDI	8.39(7.75)	10.50(7.33)	13.27(6.81)	20.39(11.08)
NRS	2.28(1.59)	4.48(1.87)	5.90(1.32)	6.98(1.00)
SCARED	12.94(6.74)	25.17(13.29)	25.23(13.73)	41.39(11.52)
Follow-up				
FDI	3.81(4.73)	3.62(3.76)	13.57(12.04)	15.05(10.35)
NRS	2.29(2.17)	2.84(2.07)	5.00(1.93)	4.12(2.34)
SCARED	16.50(9.30)	23.56(13.98)	19.50(12.45)	35.87(17.70)

Note. Values M(SD) unless otherwise indicated; FDI=Functional Disability Inventory. NRS= numeric rating scale for pain intensity; SCARED = Screen for Anxiety Related Emotional Disorders.

Table 3

Greater number of risk factors at baseline predicts functional disability levels at follow-up. Patients with 2 or 3 risk factors at baseline have significantly higher disability levels than those with 0 or 1 risk factors.

Risks	est(SE)	95% CI	
		Lower	Upper
1 vs 0	-2.237 (2.054)	-6.632	1.634
2 vs 0	6.576 (3.090) *	0.915	13.150
3 vs 0	9.546 (2.653) **	4.395	14.845
3 vs 1	-11.783 (2.526) **	-6.731	-16.835
3 vs 2	-2.97 (3.65)	-9.715	4.155
2 vs 1	-8.813 (3.058) **	-2.697	-14.929

Note.

*
p<0.05;

**
p<0.01.